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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,936	01/03/2000	THOMAS G. WILSON	082584/0107	6645

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SUTHERLAND ASBILL & BRENNAN LLP
999 PEACHTREE STREET, N.E.
ATLANTA, GA 30309

EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/402,936	WILSON ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-41,44-47,50 and 51 is/are pending in the application.
- 4a) Of the above claim(s) 15-17 and 30-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-14,28,29,44-47,50 and 51 is/are rejected.
- 7) ☒ Claim(s) 18-27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Turner et al.

Applicants claim an isolated insect polynucleotide encoding a bHLH-PAS polypeptide (Met-JHR) that is involved in binding JHIII wherein said polynucleotide hybridizes under stringent conditions to nucleotide sequences selected from sequences (SEQ ID NO:1, NO:2, etc.) encoding said bHLH-PAS polypeptides from *D. melanogaster*.

Turner et al. (previously cited, see whole article, particularly p. 136) discloses isolated cosmids that contain the Met-JHR gene from the fruit fly *D. melanogaster*. It is noted that applicants also indicate that Turner et al. prepared cosmid clones which contained the Met-JHR gene from *D. melanogaster* on p. 61 of the instant specification. Since Turner et al. and applicants isolated the same nucleic acid regions from the same organism (*D. melanogaster*), the skilled artisan would assume (absent evidence to the contrary) that the Met-JHR genomic nucleic acid sequence contained in the cosmids isolated by Turner et al. would hybridize under stringent conditions to the recited sequences encoding Met-JHR, isolated from the same organism, recited in the instant claims.

Applicants have traversed this rejection, in its previous form, by asserting that Turner et al. only served as a review of the JH literature and only roughly disclosed the genetic characterization of the JHR/bHLH (Met-JHR) nucleic acid sequence. Applicants argue that Turner et al. did not disclose the cloning, sequencing and expression of the JHR/bHLH gene and would not anticipate the instantly claimed sequences. Applicants also indicate that claim 1 has been amended to include limitations from claim 2, which was not previously rejected over Turner et al.

Applicant's arguments filed 8/22/03 have been fully considered but they are not persuasive. Initially, it is noted that claim 2 should have been rejected under 102(b) as anticipated by Turner et al. in the previous Office Action. Second, it is noted that Turner et al. did indeed clone the same region of the *D. melanogaster* genome as applicants (applicants admit this on p. 61 of the instant specification) and hence the cosmid clone recited by Turner et al. would be expected to contain (absent evidence to the contrary) the Met-JHR coding region from *D. melanogaster*. Therefore, both Turner et al. and applicants recite an isolated insect nucleic acid encoding a bHLH-PAS polypeptide (the Met-JHR gene) from the same organism. Given the scope of the instant claims, reading on any nucleic acid sequence capable of hybridizing under stringent conditions to the specific Met-JHR nucleic acid sequences applicants isolated from *D. melanogaster*, it must be considered, absent evidence to the contrary, that the sequences isolated by Turner et al. would hybridize under the recited conditions to the recited Met-JHR sequences because said sequences are from the same organism and encode the same gene product (Met-JHR protein).

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-5, 7-14, 44-47 and 50-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,326,165. Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons of record in the previous Office Action.

Applicants responded to this rejection by canceling claims 2, 6 and 43 and indicating that the instant amendments to the claims overcome the outstanding obviousness type double patenting rejection.

Applicants' response has been considered but is not sufficient to overcome the outstanding rejection. As noted in the previous Office Action, the instant claims read on polynucleotides which encode a bHLH-PAS polypeptide and are capable of hybridizing under stringent conditions to SEQ ID NO:1-3 and 6 or are capable of hybridizing to polynucleotides encoding SEQ IDNO:4-5 or are capable of hybridizing to a riboprobe

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which is the reverse transcript of a portion of SEQ ID NO:1 under stringent conditions.

Therefore, these claims read on, and include, polynucleotides which are identical to SEQ ID NO:1-3, 6 or sequences which encode SEQ ID NO:s 4-5 and hence are anticipated by the claims in the '165 patent. With regard to SEQ ID NO:7, the instant claims differ from the patented claims only in the recitation of SEQ ID NO:7 in the context of open language rather than closed language and in the context of sequences which hybridize to SEQ ID NO:7 under stringent conditions; however, the patented claims can anticipate the instant claims because the instant claims also read on a nucleic acid which can only contain the recited SEQ ID NO:7.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-29 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection, as it pertains to claims 28-29 and 50 is maintained for reasons of record in the previous Office Action and for reasons outlined below. It is noted that applicants' amendment filed 8/22/03 has overcome the outstanding rejection against claims 1, 6-8, 11-14, 18-27, 43-47 and 51.

Applicants traverse this rejection by asserting that the full length gene for SEQ ID NO:7 can be determined using routine procedures for one of skill in the art combined with the disclosures of the instant specification. Applicants indicate that amending the claims to recite nucleic acids which hybridize under stringent conditions to the disclosed nucleic acid sequences satisfies the written description requirement. Applicants provide no arguments addressing the rejection against claim 29 (reading on probes for detecting RFLPs in insect populations so as to distinguish between JH-sensitive and JH-resistant individuals). This part of the rejection is therefore maintained for reasons of record. Also, applicants do not present arguments directed to the rejection as it pertains to the lack of a written description of Met-JHR alternatively spliced isoforms. This part of the rejection is therefore maintained for reasons of record.

Applicants' arguments have been considered but are not persuasive. With regard to SEQ ID NO:7, applicants' arguments regarding the routine experimentation required to isolate the full length sequence of the Met-JHR gene from *D. erecta* appear to be directed against a enablement rejection, not a written description rejection. The issue in the present case involves whether applicants have provided an adequate written description of the sequence(s) encompassed by the claim. To reiterate, applicants disclose a portion of a putative Met-JHR coding region but claim the sequence using open language so that the claim reads on the entire coding sequence and/or the genomic sequence. The remaining sequences comprising the putative *D. erecta* Met-JHR (including the regulatory regions) must be determined empirically and cannot be determined from the disclosed portion of the coding region.

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With regard to the claim (#28) reading on the Met-JHR alternatively spliced isoforms, applicants have not provided a written description of these molecules, if they exist, because there is no structure/function relationship between these molecules and the sequences recited in claim 1. While the other sequences recited in claim 28 do have a direct structural relationship with the specific sequences recited in claim 1, the claimed Met-JHR alternatively spliced isoforms do not possess this relationship.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is vague in that applicants recite amino acid variants or polypeptides of SEQ ID NO:3; however, SEQ ID NO:3 is a polynucleotide, not a polypeptide.

Claim 51 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 51 depends from claim 1. Claim 1 is limited to nucleic acid sequences which hybridize under stringent conditions to SEQ ID NO:1-3 and 6 only. Claim 51 recites nucleic acid sequences

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which hybridize under the same stringent conditions to a different nucleic acid sequence, SEQ ID NO:7.

It is noted that applicants, in the Declaration, improperly claim benefit for the parent PCT application PCT/US98/07388 under 35 USC 119(a)-(d) rather than 35 USC 120. However, since applicants indicate, on the first page of the specification, that the instant application is a 371 national phase application of the PCT application, it is assumed that applicants mean to claim priority for the PCT under 35 USC 120.

Miscellaneous: In Claim 1, Hemiptera is misspelled as "Hemiptra".

No Claims are allowed.

Claims 18-27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo
November 12, 2003


DAVID GUZO
PRIMARY EXAMINER